REMARKS

Claims 1-32 are pending in this application. Claims 1, 7, 13, 19, and 25 have been amended without prejudice or acquiescence in order to advance prosecution of the instant application. Applicants note that the amendment of "medicinal" to "pharmaceutical" in claims 1 and 7 is tangential. Support for the claim amendments many be found on page 13, line 10, and on page 16, lines 10-15. The issues outstanding in the instant application are as follows:

- Claims 1-32 have been rejected under 35 U.S.C. § 112 second paragraph, as allegedly being failing to define the subject matter regarded as the invention.

- Claims 13, 14, 18, 19, 20, 25-28, and 32 have been rejected under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by and/or obvious over CN 1210695.

- Claims 1-20, and 25-32 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over RO 87637 in view of CN 1210695 and Remington's.

I. 35 U.S.C. § 112 issues

The Examiner has rejected claims 1-32 as failing to set forth the subject matter regarded as the invention. Applicants respectfully traverse.

Claims 1-32 distinctly point out the subject matter that Applicants regard as their invention. Applicants have amended claims without prejudice or acquiescence in order to advance prosecution of the instant application. Support for the amendments may be found in the specification on page 16, lines 10-15. Applicants respectfully request withdrawal of the 35 U.S.C. 112 rejection.

II. 35 U.S.C. § 102(b)/103(a) issues

The Examiner has rejected claims 13, 14, 18, 19, 20, 25-28, and 32 under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by and/or obvious over CN 1210695. Applicants respectfully traverse.

"A claim is anticipated only if **each and every element** as set forth in the claim is found either expressly or is inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added). "The identical invention **must be shown** in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "

CN 1210695 teaches drinking water with calcium glutarate in concentrations of 10-1,000mg/L. Applicants teach a method of inhibiting phosphorous absorption in the gastrointestinal tract by administration of an effective amount of a calcium glutarate composition in a single dose form, said composition excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. Applicants also teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract.

CN 1210695 teaches drinking water supplemented with calcium salts for nutritional value. CN 1210695 does not teach or suggest a method of inhibiting phosphorous absorption in the gastrointestinal tract. CN 1210695 does not teach or suggest compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. CN 1210695 does not teach or suggest single dose compositions. Thus, CN 1210695 does not teach or suggest all the limitations of claim 1 and there is no anticipation of claims directed towards compositions for or methods of inhibiting gastrointestinal absorption of phosphorous as taught by Applicants.

"While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification." *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) Applicants assert that the term "single dose" is well known to one skilled in the art, and thus must be given its plain meaning. As defined in Dorland's Illustrated Medical Dictionary, a

dose is "a quantity to be administered at one time." Thus, Applicants maintain that one with skill in the art would understand that a single dose is intended to be administered at one time.

As such, drinking water formulations comprising calcium salts taught by the CN 1210695 are nonequivalent to a pharmaceutical composition which comprises a single dose of calcium glutarate. For the reasons above, a single dose of the pharmaceutical composition is known to one with skill in the art to be intended for consumption at one time. Drinking water as taught by CN 1210695 that is enriched by calcium salts has no limitations indicating that consumption of any particular serving, or dose, is required. There is simply no teaching in CN 1210695 of what consumption levels of drinking water are required. Also, not only are levels of consumption not described, there is no teaching of single dose consumption of any amount of the calcium salt-enriched drinking water.

As CN 1210695 does not teach or suggest all the limitations of the claimed invention, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b)/103(a) rejection.

III. 35 U.S.C. § 102/103 issues

The Examiner has rejected claims 1-20, and 25-32, under 35 U.S.C. § 103(a) as allegedly being obvious over RO 87637 in view of CN 1210695 and Remington's. Applicants respectfully traverse.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

RO 87637A teaches medicinal composition containing multiple calcium salts, including calcium glutarate, calcium lactate, and calcium carbonate ($CaCo_3$). Remington's teaches methods of preparing pharmaceutical dosage forms, and CN 1210695 teaches calcium glutarate mineralized drinking water.

Applicants teach a method of orally administering to a person in need thereof a quantity of a composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. Applicants teach calcium glutarate compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric

acidity. Applicants also teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract.

The combined references do not teach a method of orally administering to a person in need thereof a quantity of a medicinal composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. The combined references do not teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract. The Examiner is directed to the arguments above in which it is established that single dose compositions are known to one with skill in the art to be administered at one time. The combined references do not teach calcium glutarate compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. The combined references do not teach calcium glutarate compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity.

Thus, as the combination of the references do not teach all limitations of the claimed invention, claims 1-20, and 25-32 are nonobvious. In light of the above arguments, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02490US0 from which the undersigned is authorized to draw.

Dated: January 5, 2004

Respectfully submitted,

By _____

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Dorsiflexion of foot.

dor·si·mes·al (dor″sĭ-mes′əl) dorsomesial.

dor·si·spi·nal (dor″sĭ-spi′nəl) pertaining to the back and vertebral column.

dors(o)- [L. *dorsum* back] combining form denoting relationship to a dorsum or to the back (posterior) aspect of the body. Also, *dorsi-*.

dor·so·an·te·ri·or (dor″so-an-tēr′e-ər) having the back of the fetus toward the front of the mother.

dor·so·ceph·a·lad (dor″so-sef′ə-lad) [*dorso-* + *cephalad*] directed toward the back of the head.

dor·so·dyn·ia (dor″so-din′e-ə) dorsalgia.

dor·so·in·ter·cos·tal (dor″so-in″tər-kos′təl) situated in the back and between the ribs.

dor·so·lat·er·al (dor″so-lat′ər-əl) pertaining to the back and the side.

dor·so·lum·bar (dor″so-lum′bahr) pertaining to the back and the loins, especially the region of the lower thoracic and upper lumbar vertebrae.

dor·so·me·di·an (dor″so-me′de-ən) the median line of the back.

dor·so·me·si·al (dor″so-me′se-əl) pertaining to the median line of the back.

dor·so·na·sal (dor″so-na′səl) pertaining to the dorsum of the nose or to the bridge of the nose.

dor·so·nu·chal (dor″so-noo′kəl) pertaining to the back of the neck.

dor·so·pos·te·ri·or (dor″so-pos-tēr′e-ər) having the back of the fetus directed toward the mother's back.

dor·so·ra·di·al (dor″so-ra′de-əl) pertaining to the radial or lateral side of the back of the forearm or hand.

dor·so·scap·u·lar (dor″so-skap′u-lər) pertaining to the posterior surface of the scapula.

dor·so·ven·trad (dor″so-ven′trəd) [*dorso-* + *ventrad*] directed from the dorsal toward the ventral aspect.

dor·so·ven·tral (dor″so-ven′trəl) 1. pertaining to the back and belly surfaces of the body. 2. passing from the back to the belly surface.

dor·sum (dor′səm)gen. *dor′si*, pl. *dor′sa* [L.] [TA] 1. the back. 2. the aspect of an anatomical part or structure corresponding in position to the back; posterior, in the human.
d. of foot, d. pedis.
d. of hand, d. manus.
d. lin′guae [TA], dorsum of the tongue: the upper or posterosuperior surface of the tongue.
d. ma′nus [TA], back of hand: the hand surface opposite the palm.
d. na′si [TA], dorsum of nose: that part of the external surface of the nose formed by junction of the lateral surfaces.
d. pe′dis [TA], the upper surface of the foot; the surface opposite the sole. Called also *regio dorsalis pedis* [TA alternative].
d. pe′nis [TA], **d. of penis,** the anterior, more extensive surface of the dependent penis, opposite the urethral surface.
d. of scapula, d. sca′pulae, facies posterior scapulae.
d. sel′lae [TA], the quadrilateral plate on the sphenoid bone that forms the posterior boundary of the sella turcica; the posterior clinoid processes project from its superior extremity, and it is continuous inferiorly with the clivus.
d. of testis, margo posterior testis.
d. of tongue, d. linguae.

dor·zo·la·mide hy·dro·chlo·ride (dor-zo′lə-mīd) a carbonic acid anhydrase inhibitor, used as an antiglaucoma agent in the treatment of open-angle glaucoma and ocular hypertension; administered topically to the conjunctiva.

dos·age (do′səj) the determination and regulation of the size, frequency, and number of doses.

dose (dōs) [*dosis*] 1. a quantity to be administered at one time, such as a specified amount of medication. 2. in radiology, the amount of energy absorbed per unit mass of tissue at a given site.
absorbed d., the amount of energy from ionizing radiations absorbed per unit mass of matter, expressed in rads.
air d., air exposure.
average d., the quantity of an agent which will usually produce the therapeutic effect for which it is administered.
booster d., a dose of an active immunizing agent, usually smaller than the initial dose, given to maintain immunity.
cumulative d., cumulative radiation d., the total dose resulting from repeated exposures to radiation.
curative d., a dose that is sufficient to restore normal health.
curative d., median, a dose that abolishes symptoms in 50 per cent of the test subjects. Abbreviated CD_{50}.
daily d., the total amount of a drug administered in a 24-hour period.
depth d., the intensity of radiation at a given depth in an irradiated body, expressed as a percentage of that at the surface of the body nearest the portal of entry.
divided d., fractional d.
doubling d., in radiation biology, the dose of ionizing radiation which will result in a doubling of the current rate of spontaneous biological changes, such as mutations or cancers of various kinds, in a population.
effective d., that quantity of a drug which will produce the effects for which it is administered; abbreviated ED.
effective d., median, a dose that produces the desired effect in 50 per cent of a population. Abbreviated ED_{50}.
epilating d., the amount of radiation necessary to cause temporary or permanent loss of hair.
erythema d., the amount of radiation which, when applied to the skin, causes temporary reddening of the skin.
exit d., the intensity of radiation emerging from the body at the surface opposite the portal of entry.
exposure d., see *exposure,* def. 3.
fatal d., lethal d.
fractional d., fractionated d., a fraction of the total dose prescribed of a drug or therapeutic radiation; called also *divided d.*
immunizing d., median, the dose of vaccine or antigen sufficient to provide immunity in 50 per cent of test subjects.
infective d., that amount of pathogenic microorganisms that will cause infection in susceptible subjects. Abbreviated ID.
infective d., median, the amount of pathogenic microorganisms that will produce demonstrable infection in 50 per cent of the test subjects. Abbreviated ID_{50}.
integral d., integral absorbed d., in radiation biology, the total energy absorbed by an individual or other biological object during exposure to radiation, expressed in gram-rads (100 ergs).
L+ d., L_+ d., the limes tod (death) dose, the smallest amount of diphtheria toxin that will kill a 250-gm. guinea pig within four days when mixed with one unit of diphtheria antitoxin before being injected subcutaneously. Cf. *lethal d.*
L0 d., L_0d., the limes nul or zero dose; the largest amount of diphtheria toxin that when mixed with one standard unit of antitoxin produces no perceptible reaction when injected subcutaneously into a guinea pig.
lethal d., the amount of an agent, such as a toxin or radiation, that will or may be sufficient to cause death. Called also *fatal d.* Cf. *L+ d.*
lethal d., median, the amount of pathogenic bacteria, bacterial toxin, or other poisonous substance required to kill 50 per cent of uniformly susceptible animals inoculated with it. In radiology, the amount of ionizing radiation that will kill, within a specified period, 50 per cent of individuals in a large group or population. Abbreviated LD_{50}.
lethal d., minimum (MLD), 1. the smallest amount of a toxic substance that can cause the death of a laboratory animal. 2. the smallest quantity of diphtheria toxin that will kill a guinea pig of 250 g weight in four to five days when injected subcutaneously.
Lf d., the limes flocculating dose; the amount of diphtheria toxin that in the shortest time produces precipitation when mixed with one standard unit of antitoxin.
limes nul d., limes zero d., L0 d.
Lr d., the limes reacting dose; the amount of diphtheria toxin that, when mixed with one standard unit of antitoxin, will produce a minimal skin reaction in a guinea pig.
maintenance d., a dose (often a daily dose or dosage regimen) sufficient to maintain at the desired level the influence of a drug achieved by earlier administration of larger amounts.
maximum d., the largest quantity of an agent that may be safely administered to the average patient. Cf. *tolerance d.*
maximum permissible d., MPD; the largest amount of ionizing radiation that may be received by a person in a specified period without expectation of appreciable bodily injury, according to recommended limits in current radiation protection guides; specific amounts vary with age and circumstance.
maximum tolerated d., MTD; tolerance dose.
median tissue culture infective d., that quantity of a cytopatho-